REMARKS

Favorable reconsideration is respectfully requested in view of the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-4 and 12-19 are pending in this application. These claims have been examined on the merits and stand rejected.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 2-4, 13-15 and 17-19 are rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks an enabling disclosure for the deposited the hybridomas. See page 2.

Attached herewith is a Declaration of Microorganism Availability indicating that the hybridomas have been deposited under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent as required under 37 C.F.R. § 1.808. In view of this Declaration, the rejection of claims 2-4, 13-15 and 17-19 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

Since the declaration obviates this rejection, claims 2-4 and 13 should now be allowable, as they were not included in any other rejection. Notice to that effect is hereby requested.

III. REJECTIONS UNDER 35 U.S.C. § 103

A. WO 97/26331, Roy and Thompson

Claim 1 is rejected under 35 U.S.C. § 103(a) as obvious over WO 97/26331 in view of Roy et al., the EMBO Journal, vol. 16, no. 23, pp. 6914-6925 (1997), and further in view of Thompson et al., U.S. Patent No. 6,511,828. See pages 3-4.

This rejection is respectfully traversed in view of the following remarks.

The cited references fail to render obvious the claimed invention, because they fail to teach and/or suggest each and every element of the claimed invention, namely a monoclonal antibody that specifically binds epitopes in amino acids 256-586 or 841-1052 of NAIP.

The claims call for a monoclonal antibody that specifically binds epitopes in amino acids 256-586 or 841-1052 of NAIP.

WO 97/26331 is relied upon as disclosing anti-NAIP monoclonal antibodies. These monoclonal differ from the claimed anti-NAIP monoclonal antibody according to claim 1 in that they do not specifically bind epitopes in amino acid sequence of 256-586 or 841-1052 of SEQ ID NO:1. The rejection at page 4, lines 1-2 of the Office Action even acknowledges that WO 97/26331 (i.e., the primary reference) does not teach a monoclonal antibody that specifically binds epitopes in amino acids 256-586 or 841-1052 of NAIP.

Roy is relied upon for teaching the biological importance of the BIR motif.

Thompson is relied upon for teaching that the BIR motif "lies within the epitopes the instantly claimed monoclonal antibody binds to, namely amino acids 274-349 of instant SEQ ID NO:1 (human NAIP)."

Accordingly, the cited references never produce a monoclonal antibody that specifically binds epitopes in amino acids 256-586 or 841-1052 of NAIP.

Next, the cited references lack the requisite motivation/suggestion to combine/modify the reference teachings to arrive at the claimed invention.

The rejection relies on the fact that the BIR motif lies within the epitopes the instantly claimed monoclonal antibody binds to as the alleged suggestion/motivation for generating antibodies to the BIR motif. However, there is no basis for this in the cited references. Nothing in the cited prior art teaches or suggests that the BIR motif contains epitopes, let alone, those adequate for generating monoclonal antibodies that specifically bind an epitope in amino acids 256-586 or 841-1052 of NAIP. While the cited references teach that BIR motif is biologically important for NAIP, they neither teach nor suggest that the BIR motif contains epitopes to which an antibody specifically

binds. The cited references fail to suggest that the BIR motif contains epitopes that can be used to generate the claimed monoclonal antibodies. Thus, there is no suggestion that the BIR motif disclosed in Thompson and Roy is adequate for an epitope to which an antibody specifically binds.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In this case, as discussed above, the references lack a suggestion to generate monoclonal antibodies that specifically bind to the BIR motif. To assert otherwise, amounts to nothing more than an improper obvious to try rationale. However, it is well established that in moving from the prior art to the claimed invention, obviousness cannot be based on what one of ordinary skill in the art might try or find obvious to try.

Furthermore, since the rejection lacks a suggestion to combine/modify the reference teachings to generate monoclonal antibodies that specifically bind to the BIR motif, the rejection employs impermissible hindsight. However, it is well established that the requisite motivation must come from the prior art, not an applicant's specification.

Thus, the prior art fails to provide the requisite suggestion/motivation to produce monoclonal antibodies to the specifically claimed epitope regions.

Finally, the cited references lack a reasonable expectation of success.

It is well established that a monoclonal antibody specifically binds a target protein and that the epitope of the target protein has a unique structure that the monoclonal antibody specifically recognizes.

The present invention is based on the finding that at the epitope region, amino acids 256-586 are adequate to generate a monoclonal antibody that specifically binds NAIP. In contrast, the cited prior art references fail to teach the unique structure of the epitope in amino acids 256-586 or 841-1052 of NAIP that generates a monoclonal antibody that specifically binds to it. They also fail to teach the hybridomas used to generate the monoclonal antibody of the claimed invention. Therefore,

the prior art lacks a suggestion to combine the references to arrive at the claimed invention with a reasonable expectation of success.

In view of the above, the rejection of claim 1 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

B. WO 97/26331, Roy, Thompson and Harlow

Claims 12, 14-16, 18 and 19, are rejected under 35 U.S.C. § 103(a) as obvious over WO 97/26331 in view of Roy, Thompson, and further in view of Harlow. See Office Action pages 4-5.

This rejection is respectfully traversed for the same reasons given immediately above and for the following reasons.

As discussed above, the primary reference and the Roy and Thompson references fail to teach or suggest the claimed anti-NAIP monoclonal antibody that specifically binds to the amino acid sequence of 256-586 or 841-1052 of SEQ ID NO:1. Again, the Examiner relies on Roy and Thompson for teaching biological importance of the BIR motif region 274-349. However, there is no evidence in the cited prior art that the BIR motif region contains epitopes to generate the claimed monoclonal antibody with a reasonable expectation of success.

Harlow fails to remedy its deficiency, because Harlow is merely directed towards general immunoassay methods and procedures, and mentions nothing regarding the epitopes of NAIP.

In view of the above, the rejection of claims 12, 14-16, 18 and 19 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the present application is now in condition for allowance and early notice of that effect is hereby requested. If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the below number if he has any suggestion to expedite allowance of the present application.

Respectfully submitted,

Johe IKEDA et al.

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ATTACHMENTS TO REPLY:

1. Declaration of Microorganism Availability (fully executed, 2 pp.)